

REMARKS

I. STATUS OF THE CLAIMS

Claims 8, 10-14, 45-49, and 52-54 are pending. Claims 8, 10, 11, 13, 45-49, and 52 are amended to change their dependencies. Claim 53 is amended to rephrase the proviso to exclude any antifungal agents comprising an imidazole ring. Support for that amendment can be found, for example, at paragraph [003]. Claim 54 is newly added herein. Support for that new claim can be found, for example, at paragraphs [015] and [026] and in Examples 2 and 5.

Accordingly, no new matter is added by this Amendment. Applicants therefore respectfully request that the Examiner enter these amendments.

II. REJECTIONS UNDER 35 U.S.C. § 112

A. Claims 8-14, 30, 45-49, 52 and 53

Claims 8-14, 30, 45-49, 52 and 53 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description. Of those claims, claims 8, 10-14, 45-49, 52, and 53 remain pending. The Examiner asserts that the recitation of "urea in an amount from 25 percent weight to 35 percent weight" introduces new matter.

The Examiner acknowledges the specification's teaching of 15-35 percent by weight and of 25-33 percent by weight. Office Action at 3. Accordingly, each of the limits of the claimed range is expressly disclosed in the specification. On these facts, one of ordinary skill in the art would have considered the specification to convey possession of the presently claimed ranges. Indeed, in similar situations, the M.P.E.P. acknowledges proper written support. *E.g.*, M.P.E.P. § 2163.05 (citing *In re Wertheim*,

541 F.2d 257, 191 USPQ 90 (CCPA 1976)). In *Wertheim*, the C.C.P.A. found written description support for a range of “between 35% and 60%” based on a range of “25%-60%” in the original specification and a specific example of “36%.” Accordingly, Applicants respectfully request the withdrawal of the present rejections.

B. Claim 53 - 112, First Paragraph

Claim 53 has been rejected under 112, first paragraph. Specifically, the Examiner asserts that, in the absence of a teaching or disclosure of compositions comprising antifungal imidazole derivatives, such derivatives cannot be excluded after the original filing. Office Action at 3.

In *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993), a courtesy copy of which is submitted herewith, method claims were rejected for lack of written description based on the negative limitation that a step in the method was “conducted in the absence of a catalyst.” In reversing that rejection, the Court noted that “it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an applicant had possession of the concept of what is claimed.” *Id.* at *5 (citing *In re Anderson*, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973)). The Court noted that “[t]hroughout the discussion [of the specification] which would seem to cry out for a catalyst if one were used, no mention is made of a catalyst.” *Id.* Accordingly, the Court held that the originally-filed disclosure would have conveyed to one having ordinary skill in the art the concept of conducting the claimed method step in the absence of a catalyst.

In the present case, the specification discloses compositions comprising antifungal imidazole derivatives. For example, paragraph [003] of the specification states (emphasis added)

For the detachment or dissolution of changed nails, in particular those that are fungally infested, a cream containing 20% urea (Onychomal®), and an ointment containing 40% urea and **the antimycotic Bifonazol®** (1 %)... . These preparations have been commercially available for over 10 years (Bang OS, Lee YO, Whang KK, Lee SN, "Therapeutic trial of ointment base including urea and **antifungal agent** as the treatment of onychomycosis," *Ann. Dermatol.*, 3: 32-6 (1991); Hay RJ, Roberts DT, Doherty VR, Richardson MO, Midgley G, "The topical treatment of onychomycosis using a new combined urea/**imidazole** preparation," *Glin. Exper. Dermatol.*, 13: 164-167, (1988)).

Bifonazol® is an antifungal imidazole derivative. Hay et al., of record, also used bifonazol. Bang et al., also of record, used clotrimazole, another antifungal imidazole derivative.

Accordingly, Applicants were aware and, in fact, disclosed in their specification that compositions comprising antifungal imidazole derivatives were known in the art at the time the present application was filed. However, nowhere does the specification recite that the inventive compositions comprise or even could comprise antifungal imidazole derivatives, despite repeatedly descriptions and examples of the inventive compositions. Accordingly, here, as in *Ex Parte Parks*, one of ordinary skill in the art would have understood that the presently claimed compositions did not comprise antifungal imidazole derivatives. Applicants therefore respectfully request withdrawal of this rejection.

C. Claim 53 - 112, Second Paragraph

Claim 53 was rejected under 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, allegedly because “the boundaries of “the derivatives of imidazole” is not known.” Office Action at 3.

Claim 53 has been amended to recite the proviso that the aqueous solution does not comprise any antifungal agent comprising an imidazole ring. Applicants submit that the boundaries of that component are clear and, therefore, respectfully request withdrawal of this rejection.

III. REJECTIONS UNDER 35 U.S.C. § 103(a)

1. Rejections over *Laugler et al.* (GB 2 202 743)

Claims 9-12, 30, 45-49, and 52 are rejected under 35 U.S.C. § 103(a) as obvious over *Laugler et al.* (GB 2 202 743; “*Laugler*”). Each of those claims previously depended, directly or indirectly, from independent claim 30. The dependencies of those have now been amended to depend from either independent claim 53 or 54.

Laugler is drawn to an antifungal composition comprising miconazole nitrate or econazole nitrate (see, e.g., page 1, lines 1-3), and “[b]oth miconazole nitrate and econazole nitrate are imidazole derivatives... (*id.* at lines 5-6). There is no teaching of suggestion in *Laugler* of using a composition that does not contain an antifungal imidazole derivative.

Here, however, independent claim 53 is drawn to “[a] method of hydrating brittle toenails or fingernails ...” and contains a proviso that “the aqueous solution does not

comprise any antifungal agent comprising an imidazole ring.” Accordingly, Laugler does not render claim 53 or any of its dependent claims obvious.

Similarly, independent claim 54 is drawn to “[a] method of hydrating brittle toenails or fingernails comprising applying to brittle toenails or fingernails a solution consisting of” the recited elements. The transition phrase “consisting of” excludes any element or ingredient not specified in the claim. See M.P.E.P. 2111.03 (internal citations omitted). No antifungal agents comprising an imidazole ring is specified in independent claim 54. Accordingly, Laugler, whose compositions require at least one antifungal agent comprising an imidazole ring, does not render claim 54 or any of its dependent claims obvious.

For at least those reasons, Applicants respectfully request withdrawal of this rejection.

2. Rejection over Laugler in view of Crandall (US 5,639,740)

Claims 8, 13, 14 and 30 have been rejected under 35 U.S.C. § 103(a) as obvious over Laugler, discussed above, in view of Crandall (US 5,639,740). Office Action at page 6. Applicants respectfully traverse this rejection.

Crandall is relied upon for the disclosure of a composition applied to cracked fingernails or toenails comprising lactic acid. Office Action at pages 6-7. That disclosure fails to remedy the deficiencies in Laugler discussed above. Accordingly, Applicants respectfully request withdrawal of this rejection.

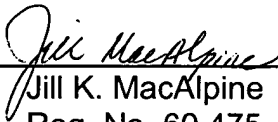
IV. CONCLUSION

In view of the amendments and remarks herein, Applicants respectfully request reconsideration of this application. Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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